

Aurobindo's Osteoporosis drug bags FDA approval

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Aurobindo Pharma Ltd announced that the company has received final approval from the US Food and Drug Administration (USFDA) to manufacture and market Risedronate Sodium Tablets USP, 5 mg, 30 mg and 35 mg (ANDA 200296).

This approval is an extension of tentative approval received on 10th October 2012. This product is ready for launch.

The approved ANDA is bioequivalent and therapeutically equivalent to the reference listed drug product (RLD) ACTONEL Tablets of Warner Chilcott.

Risedronate Sodium Tablets are used in the treatment of Osteoporosis. The approved product has an estimated market size of \$113 million for the twelve months ending October 2015 according to IMS.